NOV 23 2011

K113163

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10 510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra Inc. is providing the summary of Substantial Equivalence for the Penumbra System® MAX components.

10.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502, USA

10.2 Sponsor Contact Information

Seth Schulman
Director, Regulatory Affairs
Phone: (510) 748-3223
FAX: (510) 217-6414
Email: seth.schulman@penumbrainc.com

10.3 Date of Preparation of 510(k) Summary

October 24, 2011

10.4 Device Trade or Proprietary Name

Penumbra System® MAX

10.5 Device Classification

Regulatory Class:	II
Classification Panel:	Cardiovascular
Classification Name:	Catheter, Thrombus Removal
Regulation Number:	21 CFR §870.1250
Product Code:	NRY

10.6 Predicate Devices

510(k) Number / Clearance Date	Name of Predicate Device	Name of Manufacturer
K072718 [28Dec2007]	Penumbra System [026, 032, 041]	Penumbra, Inc.
K090752 [21Sep2009]	Penumbra System [054]	Penumbra, Inc.
K100769 [21May2010]	Penumbra System Separator Flex [026, 032, 041, 054]	Penumbra, Inc.

10.7 Device Description

The Penumbra System MAX components are additional components of the currently available Penumbra System. The Penumbra System MAX components provide a larger lumen to assist in the efficient removal of thrombus from the

brain. The devices are provided sterile, non-pyrogenic, and intended for single use only.

10.8 Intended Use

The Penumbra System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.

10.9 Summary of Non-Clinical Data

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, a summary of any information regarding safety and effectiveness of the device follows.

Included in this section are descriptions of the testing's, which substantiates the safe and effective performance of the Neuron MAX System as well as its substantial equivalence to the predicate devices:

- Biocompatibility
- Design Verification (Bench-Top Testing)
- Animal Study

The subject Penumbra System MAX components met all established requirements.

10.9.1 Biocompatibility Testing

The Penumbra System MAX components were classified in accordance with ISO 10993 -1 guidelines (Biological Evaluation of Medical Devices) for limited duration (<24 hours), external-communicating devices, contacting circulating blood. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. In summary, non-clinical testing found the Penumbra System MAX components to be biocompatible according to the requirements of ISO 10993 requirements, including:

Test	Method	Results
In Vitro Cytotoxicity	ISO Elution Test (MEM Extract)	No evidence of cell lysis or toxicity
Acute Intracutaneous Reactivity (Irritation)	ISO Intracutaneous (Intradermal) Injection Test	No evidence of irritation
Acute Systemic Toxicity	ISO Acute Systemic Injection Test	No evidence of systemic toxicity
Rabbit Pyrogen Study	USP Material-Mediated Rabbit Pyrogen Test	No evidence of material-mediated pyrogenicity
Sensitization	ISO Maximization Test for Delayed Hypersensitivity	Non-Sensitizing
Hemo-compatibility		
-*In Vitro* Hemolysis	ASTM Methode (Extraction & Direct Contact)	Non-hemolytic
-*In Vitro* Coagulation (PT, PTT)	Prothrombin Time (PT) Assay	Coagulation times are within the normal rang
	Partial Thromboplastin Time (PTT) Assay	Non-Thrombogenic
-Complement Activation	C3a and SC5b-9 through Enzyme Assay	No greater biological response than corresponding control

10.9.2 Bench-top Testing

The physical, mechanical and performance testing of the Penumbra System MAX components demonstrates that the devices are substantially equivalent to the currently marketed predicate devices:

Design Verification testing was conducted to evaluate the physical and mechanical properties of the Penumbra System MAX components. All studies were conducted using good scientific practices and statistical sampling methods as required by the Penumbra Design Control procedures. All testing was performed using units which were 2x sterilized and met finished goods release requirements. The tests performed on the Penumbra System MAX components included:

Design Verification (Bench-Top Testing) Summary – Reperfusion Catheters

Test / Test Subject	Attribute	Sample Size	Result
Pouch Seal	Pouch Seal Strength	30	Pass
Dimensional / Visual Inspection	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.		Pass
Simulated Use [Intracranial Access & Thrombus Removal]	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.		Pass
Reperfusion Catheter 3MAX / Reperfusion Catheter 4MAX	Hub /Shaft & Hub / HypotubeTensile Strength	30	Pass
Reperfusion Catheter 3MAX / Reperfusion Catheter 4MAX	Joint Tensile Strength	30	Pass
Reperfusion Catheter 3MAX / Reperfusion Catheter 4MAX	Hub Air Aspiration	30	Pass
	Burst Test	30	Pass
Reperfusion Catheter 3MAX / Reperfusion Catheter 4MAX	Particulate Testing (Hydrophilic Coating)	10	Pass
Reperfusion Catheter4MAX/ Sheath or 8F Guide compatibility (Friction Force)	Friction Force	30	Pass
Reperfusion Catheter 4MAX/ 0.014" Guidewire compatibility (Friction Force)			Pass
Reperfusion Catheter 3MAX/ Reperfusion Catheter 054 (Friction Force)			Pass
Reperfusion Catheter 3MAX/ 0.014" Guide wire compatibility (Friction Force)			Pass
Reperfusion Catheter 3MAX / Reperfusion Catheter 4MAX	Flow Rate	3	Pass
Reperfusion Catheter 3MAX / Reperfusion Catheter 4MAX	Elongation to Failure	30	Pass
Reperfusion Catheter 3MAX / Reperfusion Catheter 4MAX	Corrosion	30	Pass
Reperfusion Catheter 3MAX / Reperfusion Catheter 4MAX	Torsion	30	Pass

Design Verification (Bench-Top Testing) Summary – Separator 3MAX

Test / Test Subject	Attribute	Sample Size	Result
Dimensional / Visual Inspection (all sizes)	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.		Pass
Simulated Use: Reperfusion Catheter 3MAX / Separator 3MAX / Aspiration Tubing Assembly Performance	Hub Transition	N=30	Pass
	Tracking	N=30	Pass
	Separator 3MAX & Reperfusion Catheter Compatible	N=30	Pass
	Separator 3MAX / Reperfusion Catheter / Pump and accessories / Aspiration Tubing (Aspiration Remove Clot)	N=30	Pass
	Separator 3MAX and Reperfusion Catheter	N=30	Pass

Test / Test Subject	Attribute	Sample Size	Result
	Compatibility (Separator Advance / Retract)		
Separator Bond Joint Test	Separator 054 and Wire Joint Break Force	N=30	Pass
	Separator 041 and Wire Joint Break Force	N=30	Pass
	Separator 032 and Wire Joint Break Force	N=30	Pass
	Separator 026 and Wire Joint Break Force	N=30	Pass
	Separator 3MAX and Wire Joint Break Force	N=30	Pass

The results of the tests appropriately address the physical and mechanical performance expectations of the device. This is further supported by the surgical handling and performance results reported in the *in vivo* study. Based on these overall results, the physical and mechanical properties of the Penumbra System MAX components are acceptable for the intended use and substantially equivalent to the predicate devices.

10.9.3 Animal Study

An animal study was conducted to evaluate the safe use of the Penumbra System MAX in a swine model. The study concluded that:

- No vessel injury was noted on the final angiograms following the vessel response procedure.
- No abnormal gross or histology findings were noted in test vessel segments.
- The use of the Penumbra System MAX components resulted in no significant vascular response in these experimental conditions.

10.9.4 Summary of Substantial Equivalence

The Penumbra System MAX components are substantially equivalent to the predicate devices with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Penumbra, Inc.
c/o Mr. Seth A. Schulman
Director, Regulatory Affairs
1351 Harbor Bay Parkway
Alameda, CA 94502

NOV 23 2011

Re: K113163
Trade/Device Name: Penumbra System® MAX
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: October 25, 2011
Received: October 26, 2011

Dear Mr. Schulman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

11 Statement of Indication for Use

Indications for Use

510(k) Number (if known): K113163

Device Name: Penumbra System® MAX

Indications for Use:

The Penumbra System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.

Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JEFFREY TOY

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113163